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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/285,429	04/02/99	SHIRLEY	B 5784-9

HM22/1228

CHIRON CORPORATION
INTELLECTUAL PROPERTY - R440
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EXAMINER	
MOEZIE,F	
ART UNIT	PAPER NUMBER
1653	14

DATE MAILED: 12/28/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/285,429	Applicant(s) Shirley
	Examiner F. T. Moezie	Group Art Unit 1653

☒ Responsive to communication(s) filed on *10/15/99, 6/28/00, 7/17/00 and 10/23/00* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-20* is/are pending in the application.

Of the above, claim(s) *15-20* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-14* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-20* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *6 & 8*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- *SEE OFFICE ACTION ON THE FOLLOWING PAGES* ---

DETAILED ACTION

STATUS OF CLAIMS

Claims 1-14 are pending prosecution in this Office action.

Claims 1-20 were originally filed. In response to the Office action Restriction Requirement/Species Election (mailed 5/12/00) applicant elected Group I Invention, claims 1-10 and 13-14 (07/17/00), without traverse. In response to the Specie Election, applicant elected specie of IGF-I (10/23/00).

Because the elected specie is claimed in claims 11 and 12, Group II invention, Groups I and II Inventions, claims 1-14, are examined together in this Office action.

Claim 15-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11, received 7/7/00.

The Restriction Requirement is made ***Final.***

In response to this Office action, applicant is advised to cancel claims to non-elected inventions.

REJECTION - 35 USC FIRST AND SECOND PARAGRAPHS

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

> make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for IGF-I, does not reasonably provide enablement for all other pharmaceutically ***active agents*** (organic and inorganic agents) nor the ***biologically active variants*** of IGF-I. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The terminology "***pharmaceutically active agent***" render the claims (1-10, 13 and 14) indefinite as to the claims' metes and bounds. See page 8, first paragraph, wherein the agents encompass organic and inorganic agents. It is not clear as to which organic or inorganic agents are intended to claim in the claims.

In claims 9 and 10, the term "such that" render the claims indefinite as to how.

In claims 11 and 12 the terminology "a biologically active variant thereof" render the claims indefinite as to what they are and the claims metes and bounds.

REJECTION - 35 USC 102 (b) AND 35 USC 103 (a)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by EPA 0 284 249, published 09/1988.

The reference discloses a composition comprising a pharmaceutically active compound (an interferon) and a succinate buffer and a counter ion (abstract). See, the entire document, especially page 4, Examples and the claims.

Because the claims are drawn to a subject matter taught by the art, the claims are anticipated by the art.

Claims 11 and 12 are rejected under 35 USC 102 (b) as being anticipated by Clark et al in US Patent NO. 5,374,620.

The Patent teaches a composition comprising IGF-I, sodium chloride and succinate buffer "or any others known to the art to have the desired effect" at pH of about 6 (col. 15, line 1). See, the entire document, especially the examples and results.

The claims being drawn to a subject matter taught by the art, are anticipated by the art.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,374,620 to Clark et al, issued Dec.20,1994 and EPA 0284 249.

The '620 document teaches that a composition comprising IGF-I and succinate buffer containing a counter ion (Na+) at pH of about 3-8 is known in the art (col. 6-7).

However, the reference does not teach that succinate buffer will contribute to a greater stability in the resulting composition. The EPA discloses that use of succinate buffer contributes greatly to the stability of a composition comprising a pharmaceutically active compound..

One of ordinary skill in the art at the time the invention was made would have been motivated to use succinate buffer in the composition of '620 for imparting greater stability to the resulting composition.

CONCLUSION

claims 1-14 are not allowed.

Any inquiry concerning this communication should be directed to F.T. Moezie at telephone number (703) 305-4508.

F. T. Moezie

PRIMARY EXAMINER
ART UNIT 1653